

1 Andy D. Birchfield, Jr. (BIR006)  
2 Gerald B. Taylor, Jr. (TAY026)  
3 Navan Ward, Jr. (WAR062)  
4 BEASLEY, ALLEN, CROW, METHVIN,  
5 PORTIS & MILES, P.C.  
6 Post Office Box 4160  
7 Montgomery, Alabama 36103-4160  
8 (334) 269-2343 telephone  
9 (334) 954-7555 facsimile  
10  
11 Attorneys for Plaintiff

FILED

07 JUL 16 PM 3:12

RICHARD W. WIEKING  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

E-Filing

12 IN THE UNITED STATES DISTRICT COURT  
13 FOR THE NORTHERN DISTRICT OF CALIFORNIA  
14 (SAN FRANCISCO DIVISION)

15 IN RE: BEXTRA AND CELEBREX  
16 MARKETING SALES PRACTICES AND  
17 PRODUCT LIABILITY LITIGATION

MDL No. 1699

18 CARBALLO, RACHEL (NM);  
19 CERVO, MERLE LEE (NM);  
20 IVESTER, REBECCA LEE (SC);  
21 MARKS, JIMMY (FL);  
22 PEREZ, ELIZABETH (FL);  
23 SHARP, WILLIAM WADE (AR);  
24 ZEIDAN, SOUHEIL (FL);

Plaintiff,

v.

25 PFIZER, INC., PHARMACIA  
26 CORPORATION, G.D. SEARLE LLC, (FKA  
27 G.D. SEARLE & CO.), and MONSANTO  
28 COMPANY,

Defendants.

Case No.

CIVIL COMPLAINT

JURY TRIAL DEMANDED

29 Plaintiffs Rachel Carballo, Merle Lee Cervo, Rebecca Lee Ivester, Jimmy Marks,  
30 Elizabeth Perez, William Wade Sharp and Souheil Zeidan by and through their counsel, bring this  
31 action against Defendants PFIZER, INC., PHARMACIA CORP., MONSANTO COMPANY,  
32 and G.D. SEARLE LLC. (hereinafter collectively "Defendants") and allege as follows:

## I. PARTIES

1. This is an action for damages arising from Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe medication Celecoxib, trade name CELEBREX® ("CELEBREX").

2. Plaintiff Rachel Carballo was at all relevant times adult resident citizen of the State of New Mexico, County of Rio Arriba. Plaintiff was prescribed and began taking CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious cardiovascular injury or heart attack on or about August 12, 2004, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

3. Plaintiff Merle Lee Cervo was at all relevant times adult resident citizen of the State of New Mexico, County of Colfax. Plaintiff was prescribed and began taking CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious cardiovascular injury or heart attack on or about October 9, 2002, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

4. Plaintiff Rebecca Lee Ivester was at all relevant times adult resident citizen of the State of South Carolina, County of Anderson. Plaintiff was prescribed and began taking CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious cardiovascular injury or heart attack on or about July 9, 2002, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

5. Plaintiff Jimmy Marks was at all relevant times adult resident citizen of the State of Florida, County of Pinellas. Plaintiff was prescribed and began taking CELEBREX for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious cardiovascular injury or heart attack on or about August 6, 2001, which has caused and will continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

1           6.       Plaintiff Elizabeth Perez was at all relevant times adult resident citizen of the State  
2 of Florida, County of Pasco. Plaintiff was prescribed and began taking CELEBREX for the  
3 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe  
4 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious  
5 cardiovascular injury or heart attack on or about July 14, 2001, which has caused and will  
6 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

7           7.       Plaintiff William Wade Sharp was at all relevant times adult resident citizen of the  
8 State of Arkansas, County of Craighead. Plaintiff was prescribed and began taking CELEBREX  
9 for the treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered  
10 severe cardiovascular injuries while taking CELEBREX, including, but not limited to, serious  
11 cardiovascular injury or heart attack on or about December 13, 2001, which has caused and will  
12 continue to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

13           8.       Plaintiff Souheil Zeidan was at all relevant times adult resident citizen of the State  
14 of Florida, County of Lee. Plaintiff was prescribed and began taking CELEBREX for the  
15 treatment of pain. As a direct and proximate result of using CELEBREX, Plaintiff suffered severe  
16 cardiovascular injuries while taking CELEBREX, including, but not limited to, serious  
17 cardiovascular injury or heart attack on or about July 7, 2003, which has caused and will continue  
18 to cause Plaintiff damages and places Plaintiff at risk of further serious injury or death.

19           9.       Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place  
20 of business in New York, New York. In 2003, Pfizer acquired Pharmacia Corporation for nearly  
21 \$60 billion. At all relevant times Pfizer and/or its predecessors in interest were engaged in the  
22 business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and  
23 selling the drug Celecoxib, under the trade name CELEBREX in California and nationwide.

24           10.      Defendant G. D. Searle, LLC, formerly known as G. D. Searle & Co. ("Searle") is  
25 a Delaware corporation with its principal place of business in Illinois. At all relevant times,  
26 Searle has been engaged in the business of marketing and selling CELEBREX nationwide and in  
27 California. Searle is a subsidiary of Pfizer, acting as its agent and alter ego in all matters alleged  
28 within this Complaint.

11. Defendant Monsanto Company ("Monsanto") was the parent corporation of Searle and is a Delaware corporation. At all times relevant hereto, Monsanto, through its subsidiary companies, was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product CELEBREX nationwide.

12. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia, and its predecessors in interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, and selling CELEBREX nationwide and in California.

## II. JURISDICTION AND VENUE

13. This is an action for damages, which exceeds seventy-five thousand dollars (\$75,000.00).

14. There is complete diversity of citizenship between the Plaintiffs and Defendants. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds \$75,000.00, and because there is complete diversity of citizenship between Plaintiffs and Defendants.

15. Venue is proper in this United States Judicial District pursuant to 28 U.S.C.A. § 1391. Defendants marketed, advertised and distributed the dangerous product in the district, thereby receiving substantial financial benefit and profits the dangerous product in this district, and reside in this district under 28 U.S.C.A. § 1391(c), such that venue is proper.

16. At all relevant times herein, Defendants were in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX. Defendants at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce the aforementioned prescription drug. Defendants do substantial business Nationwide and within this Federal Judicial District, advertise in this district, receive substantial compensation and profits from sales of CELEBREX in this District, and made material omissions and



misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct alleged herein each defendant acted as the agent for each of the other defendants, or those defendant's predecessors in interest.

### III. INTERDISTRICT ASSIGNMENT

17. Assignment to the San Francisco Division is proper as this action is related to *In Re: Celebrex and Celebrex Marketing Sales Prac. and Pro. Liab. Lit.*, MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. (See also, MDL-1699 Pretrial Order No. 2)

### IV. FACTUAL BACKGROUND

#### A. Facts Regarding All Plaintiffs

18. Plaintiffs and Plaintiffs' healthcare providers were at the time of Plaintiffs' injuries unaware - and could not have reasonably known or have learned through reasonable diligence - that such injury directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and misrepresentations or from Plaintiffs' ingestion of CELEBREX.

19. Plaintiffs used CELEBREX in a proper and reasonably foreseeable manner and used it in a condition that was substantially the same as the condition in which it was manufactured and sold.

20. Plaintiffs would not have used CELEBREX had Defendants properly disclosed the risks associated with the drug.

#### B. Facts Regarding CELEBREX: Science and other Cox-2 Inhibitors

15. CELEBREX is one of a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve), and ibuprofen (trade name Advil) are examples of well-known NSAIDs.

16. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclo-oxygenase or "COX." There are two forms of COX enzymes—COX-1 and COX-2. Aspirin, naproxen and ibuprofen all act by blocking COX-1 and COX-2 enzymes.

1           17. In addition to decreasing inflammation, the prostaglandins that are supported by  
2 COX-1 enzymes are involved in the production of gastric mucus; this protects the stomach wall  
3 from the hydrochloric acid present in the stomach. It is generally accepted in the medical  
4 community that by blocking the COX-1 enzyme, the body's ability to protect gastric tissue is  
5 hampered and as a result, can cause harmful gastrointestinal side effects, including stomach  
6 ulceration and bleeding.

7           18. Prostaglandin I<sub>2</sub> is the predominant cyclooxygenase product in endothelium,  
8 inhibiting platelet aggregation (preventing clot formation), causing vasodilation, and preventing  
9 the proliferation of vascular smooth muscle. Whereas older NSAIDS inhibit Thromboxane A<sub>2</sub>  
10 and Prostaglandin I<sub>2</sub>, the COX-2 inhibitors leave Thromboxane A<sub>2</sub> unaffected. Thromboxane A<sub>2</sub>  
11 is a potent platelet aggregator and vasoconstrictor which is synthesized by platelets. Therefore,  
12 while the older NSAIDS suppress platelet aggregation and vasoconstriction, the COX-2 inhibitors  
13 support it.

14           19. Traditional NSAIDs like aspirin reduce pain/inflammation and therefore pain by  
15 inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional  
16 NSAIDs may cause ulcers in the stomach. However, traditional NSAIDs do not cause blood  
17 clots, rather they actually reduce the risk of clots and help protect heart function.

18           20. Defendants and other pharmaceutical companies set out to remedy these ulcer and  
19 bleeding problems suffered by some NSAID users by developing "selective" inhibitors that  
20 would block only COX-2 production, thus (supposedly) allowing the proper maintenance of  
21 gastric tissue while still reducing inflammation.

22           21. In making this decision, Defendants and their predecessors in interest either  
23 intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2  
24 inhibition lowers prostacyclin levels and causes thromboxane A<sub>2</sub> to be uninhibited, causing blood  
25 clots, and giving rise to various clot-related cardiovascular events, including heart attack, stroke,  
26 unstable angina. The vasoconstriction and fluid retention cause the hypertension.

1           22. Pfizer launched CELEBREX, the first of the three major COX-2 inhibitor drugs, in  
2 January 1999 and initiated a massive marketing campaign to convince doctors and consumers of  
3 the superiority of their new “blockbuster” drug over less inexpensive NSAIDs. In May, 1999,  
4 Merck & Co., Inc. (“Merck”) launched Vioxx, its own selective COX-2 inhibitor.

5           23. Seeking increased market share in this extremely lucrative market, Defendants,  
6 and their predecessors in interest, also sought approval of a “second generation” selective COX-2  
7 inhibitor and filed for FDA approval of Celecoxib (Celebrex) on January 16, 2001 for the  
8 (i) prevention and treatment of acute pain, (ii) treatment of primary dysmenorrhea, and (iii) relief  
9 of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis.

10 **C. Facts Regarding CELEBREX’s Safety and Defendants’ Knowledge Thereof**

11           24. The potential for cardiovascular risk of selective COX-2 inhibitors was known to  
12 Defendants long before the market launch. By 1997, and prior to the submission of the New  
13 Drug Application (the “NDA”) for CELEBREX, Defendants was aware that, by inhibiting COX-  
14 2, CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane  
15 and thereby, increased the prothrombotic effects of the drugs, causing blood clots to form in those  
16 who ingested it. *See Topol, E.J., et al., Risk of Cardiovascular Events Associated with Selective*  
17 *Cox-2 Inhibitors, JAMA*, August 22, 2001 at 954.

18           25. As Pharmacologist, Dr. Garrett Fitzgerald, of the University of Pennsylvania,  
19 reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004,  
20 that it was known as early as 1999 that selective COX-2 inhibitors, such as CELEBREX,  
21 suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation  
22 in vitro, and may predispose patients to myocardial infarction or thrombotic stroke.

23           26. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and  
24 basic research on this type of selective inhibitor which had been widely conducted, Defendants  
25 knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed  
26 serious cardiovascular risks for anyone who took them, and presented a specific additional threat  
27  
28

1 to anyone with existing heart disease or cardiovascular risk factors. Studies show that selective  
2 COX-2 inhibitors, including CELEBREX, decrease blood levels of a prostacyclin. When those  
3 levels fall, the arteries are more vulnerable to clotting, high blood pressure, heart attack, and  
4 stroke.

5 27. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing  
6 new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action  
7 to protect the health and welfare of patients, but instead, continued to promote the drug for sale  
8 even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug  
9 Advisory Committee meetings.

10 **1. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

11  
12 28. The defendants touted the CELEBREX Long-Term Arthritis Safety Study  
13 ("CLASS") as the primary evidence to support its theory that CELEBREX was safer for  
14 consumers that could not tolerate traditional NSAIDs in their gastrointestinal system. (CLASS  
15 data is found in NDA 20-998/S-009 submitted to the FDA by G.D. Searle on June 12, 2000.  
16 CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D.  
17 (FDA Medical Officer) on September 20, 2000.)

18 **2. CLASS**

19 29. The FDA Medical Officer Review of the CLASS data proves CELEBREX is no  
20 more efficacious than other traditional NSAIDs and is harmful to consumers. See generally,  
21 FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by G.D. Searle on  
22 June 12, 2000 ("FDA CLASS Review"). On April 7, 2005, the FDA issued an *Alert* noting only  
23 minimal information is available regarding CELEBREX: "The only available data from a long  
24 term comparison of CELEBREX to other NSAIDs came from the CLASS study...."

25 30. Pfizer misrepresented the data in CLASS by using biased authors. According to  
26 the *Washington Post* the CLASS authors were either employees of Pharmacia, CELEBREX's  
27 manufacturer, or paid consultants of the company. Pfizer needed a study to demonstrate that its  
28 Cox-2 inhibitor was safer for the stomach than older cheaper medications: CLASS was designed



1 to be that study. Unfortunately, the results of the completed study revealed the truth –  
2 CELEBREX offered no gastrointestinal (GI) benefit. Instead of releasing the complete –12-  
3 month – results from CLASS, Pfizer had only the first six months of data published in the Journal  
4 of American Medicine. JAMA 2000,48:1455-1460.

5 31. 40. “After reviewing the full study, the FDA’s arthritis advisory committee  
6 concluded that CELEBREX offers no proven safety advantage over the two older drugs in  
7 reducing the risk of ulcer complications, said FDA spokesman Susan Cruzan.” *Washington Post*,  
8 August 5, 2001. According to the FDA’s review of the CLASS data: “Celecoxib did not  
9 demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and  
10 ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper  
11 Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored  
12 celecoxib” (FDA CLASS Review)

13 32. According to an August 5, 2001 article in the *Washington Post*, editors of the  
14 Journal of the American Medical Association (JAMA) and other medical experts, “were  
15 flabbergasted” when they realized they had been duped by only being provided with the first six  
16 months of CLASS data. The Washington Post reported JAMA editors as saying: “When all of the  
17 data were considered, most of CELEBREX’s apparent safety advantage disappeared.”

18 33. The “scientific double-cross” boosted sales. “[T]he JAMA article and editorial  
19 have likely contributed to CELEBREX’s huge sales. ‘When the JAMA article comes out and  
20 confirms the hype, that probably has more impact than our labeling does,’ said Robert J. Temple,  
21 director of medical policy at the FDA’s Center for Drug Evaluation and Research.” *Washington*  
22 *Post*, August 5, 2001.

23 34. “A total of 36 deaths occurred during the [CLASS] study or during post study  
24 follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . .  
25 Most deaths were cardiovascular in nature.” FDA CLASS Review, at 54. The increased number  
26 of adverse cardiovascular events in the CELEBREX group was not surprising as they were also  
27 revealed in the original New Drug Application (NDA) submitted for CELEBREX. “In the  
28 original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as

1 compared to placebo treated patients. In the long term trial (Trial 024) that was included in the  
2 NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any  
3 does was cardiovascular.” FDA CLASS Review at 78.

4 35. Public Citizen, a public watchdog organization, reviewed the CLASS data in its  
5 entirety. A complete review reveals the combined anginal adverse events were 1.4% in celecoxib  
6 (CELEBREX) group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in  
7 the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

8 36. The CLASS data proves that Pfizer knew that its first generation Cox-2 inhibitor,  
9 CELEBREX, caused a disproportionately and statistically significantly high number of adverse  
10 cardiovascular events before it was introduced to the market in January 1999. According to  
11 Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the CV risk of  
12 COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this  
13 placebo-controlled trial of CELEBREX.

### 14 3. APC Trial

15 37. The Adenoma Prevention with Celecoxib (APC) trial compared the efficacy and  
16 safety of celecoxib with placebo. N.ENG. J. MED. 352;11 at 1072. According to the APC trial, the  
17 number of deaths from cardiovascular causes was significantly higher in the CELEBREX group  
18 when compared to placebo. (0.1% placebo; 0.4% CELEBREX 200mg; and 0.9% CELEBREX  
19 400mg). Id. at 1075.

20 38. The FDA Reported the APC data as follows<sup>1</sup>:

- 21
- 22 i. In the National Cancer Institute’s Adenoma Prevention with  
23 Celecoxib (APC) trial in patients at risk for recurrent colon  
24 polyps, a 2-3 fold increased risk of serious adverse CV  
25 events was seen for CELEBREX compared to placebo after  
26 a mean duration of treatment of 33 months. There appeared  
27 to be a dose response relationship, with a hazard ratio of 2.5  
28 for CELEBREX 200 mg twice daily and 3.4 CELEBREX  
400 mg twice daily for the composite endpoint of death  
from CV causes, myocardial infarction (MI), or stroke.

39. The dosage noted in the study is important for two reasons: first, there appears to

<sup>1</sup> April 7, 2005 FDA Alert: [www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm](http://www.fda.gov/cder/drug/infopage/CELEBREX/CELEBREX-hcp.htm).

1 be an association between dosage and the increase in adverse cardiovascular events. See  
2 generally, at 1077. Second, most patients increase dosage. Pfizer knew patients were increasing  
3 their dosages as noted in CLASS: “Interestingly ... up to 70% of patients increased their dose for  
4 celecoxib.” FDA CLASS Review at 74. Thus, Pfizer was aware of the dosage creep.

#### 5 **4. Other CELEBREX Trials**

6 40. Several other CELEBREX trials also gave Defendants insight into the  
7 cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous  
8 Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke,  
9 heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7%  
10 for placebo.

11 41. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which  
12 reflected “the combined rate of all serious cardiovascular adverse events in patients getting a  
13 placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold  
14 increase in CV risk in those people taking celecoxib. (p=0.03)”<sup>2</sup>. According to Dr. Sidney Wolfe,  
15 “The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and  
16 more than a doubling in the rate of CV deaths in people using celecoxib compared to those using  
17 placebo.”<sup>3</sup>

#### 18 **5. Cox-2 Studies: VIGOR and APPROVe**

19 42. Pfizer also had access to other data which indicated a cardiovascular risk with its  
20 drugs. Specifically, Pfizer had knowledge of two studies conducted by Merck related to its Cox-2  
21 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp  
22 Prevention (APPROVe).

##### 23 **a. VIGOR**

24 43. In 2000, The FDA Medical Officer Review of CLASS specifically noted the  
25 VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at  
26 78.

27  
28 <sup>2</sup> *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe.

<sup>3</sup> *Id.*

1           44. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes  
2 Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically  
3 significant); they experienced 4.6 times more hypertension events serious enough to warrant  
4 discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure  
5 adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice  
6 the risk of naproxen and the results were considered statistically significant.

7           45. The VIGOR study comprised the most definitive scientific evidence ever obtained  
8 about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of  
9 medical research. It was a safety study with endpoints set in advance. As Merck stated many  
10 times, it was designed to provide definite proof of safety, convincing enough to silence the most  
11 skeptical critics. In medical terms, the VIGOR results raised the question of whether selective  
12 inhibition of Cox-2 was a monumental mistake from the start. While the NSAID risks to the GI  
13 system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the  
14 arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including  
15 Defendants, were aware of these results.

16                   **b. APPROVe**

17           46. Anxious to put safety questions surrounding Vioxx to rest, Merck designed  
18 another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test  
19 the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular  
20 safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of  
21 the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and  
22 "doubled the risk of MI (myocardial infarction a/k/a heart attack)<sup>4</sup>. *Public Citizen*, January 24,  
23 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx,  
24 Pfizer never paused to re-evaluating the CELEBREX data and studies.

25  
26  
27           <sup>4</sup> Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did  
28 not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant  
increase in risk of heart attack was evident in as little as 4 months time.



1           47. The scientific data available during and after CELEBREX's approval process  
2 made clear to Defendants that their formulation of CELEBREX would cause a higher risk of  
3 blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to  
4 the need to do additional and adequate safety studies.

5           48. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of*  
6 *Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing  
7 to humans "... it is mandatory to conduct a trial specifically assessing cardiovascular risk and  
8 benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established  
9 coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and  
10 have the highest risk of further cardiovascular events."

11           49. Dr. Topol was also the author on the study published in August 2001 in JAMA  
12 (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who  
13 used COX-2 inhibitors.

14           50. Based upon readily available scientific data, Defendants knew, or should have  
15 known, that their pre-approval testing of CELEBREX did not adequately represent the cross-  
16 section of individuals who were intended consumers and therefore, likely to take CELEBREX.  
17 Therefore, Defendants' testing and studies were grossly inadequate.

18           51. Had Defendants done adequate testing prior to approval and "market launch,"  
19 rather than the extremely short duration studies done on the small size patient base that was  
20 actually done the defendants' scientific data would have revealed significant increases in  
21 incidence of strokes and myocardial infarctions among the intended and targeted population of  
22 CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed  
23 serious side effects. Defendants should have taken appropriate measures to ensure that their  
24 defectively designed product would not be placed in the stream of commerce and/or should have  
25 provided full and proper warnings accurately and fully reflecting the scope and severity of  
26 symptoms of those side effects should have been made.

1           52. In fact, post-market approval data did reveal increased risks of clotting, stroke and  
2 myocardial infarction, but Defendants intentionally suppressed this information in order for them  
3 to gain significant profits from continued CELEBREX sales.

4           53. Defendants' failure to conduct adequate testing and/or additional testing prior to  
5 "market launch" was based upon their desire to generate maximum financial gains for themselves  
6 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

7           54. At the time Defendants manufactured, advertising, and distributed CELEBREX to  
8 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
9 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
10 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but  
11 instead would purchase other cheaper and safer NSAIDs.

12 **D. Facts Regarding Defendants' Marketing and Sale of CELEBREX**

13           55. Such an ineffective and unreasonably dangerous drug could only be widely  
14 prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the  
15 Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and  
16 misleading advertising, consumers, including the Plaintiff, would not have purchased  
17 CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

18           56. On January 10, 2005 the FDA issued Pfizer a written reprimand for its  
19 promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and  
20 2 Celebrex] variously: omit material facts ... and make misleading safety, unsubstantiated  
21 superiority, and unsubstantiated effectiveness claims." This was not the Defendants first offense  
22 related to its Cox-2 inhibitors. The FDA also reprimanded Pfizer on October 6, 1999 noting:  
23 "DDMAC has reviewed these promotional pieces and has determined that they are false or  
24 misleading because they contain unsubstantiated comparative claims, misrepresentations of  
25 CELEBREX's safety profile, and are lacking in fair balance." Ultimately, on April 8, 2005, the  
26 New York Times reported the results of an FDA advisory panel: "The February advisory panel  
27 voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."  
28

1           57. At all times relevant herein, Defendants engaged in a marketing campaign with the  
2 intent that consumers would perceive CELEBREX as a safer and better drug than its other  
3 NSAIDs and, therefore, purchase CELEBREX.

4           58. Defendants widely and successfully marketed CELEBREX throughout the United  
5 States by, among other things, conducting promotional campaigns that misrepresented the  
6 efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was  
7 represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems.  
8 Defendants made misrepresentations by means of media advertisements, and statements  
9 contained in sales literature provided to Plaintiff's prescribing physicians.

10           59. Despite knowledge of the dangers presented by CELEBREX, Defendants and  
11 Defendants' predecessors in interest, through their officers, directors and managing agents for the  
12 purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy  
13 the known defects of Defendants' product, CELEBREX, and failed to warn the public, including  
14 Plaintiff, of the serious risk of injury occasioned by the defects inherent in Defendants' product,  
15 CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with  
16 the inadequate safety testing, and then the manufacturing, sale and marketing of Defendants'  
17 product, CELEBREX, knowing that persons would be exposed to serious potential danger, in  
18 order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and  
19 displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

20           60. In an elaborate and sophisticated manner, Defendants aggressively marketed  
21 CELEBREX directly to consumers and medical professionals (including physicians and leading  
22 medical scholars) in order to leverage pressure on third party payors, medical care organizations,  
23 and large institutional buyers (e.g., hospitals) to include CELEBREX on their formularies. Faced  
24 with the increased demand for the drug by consumers and health care professionals that resulted  
25 from Defendants' successful advertising and marketing blitz, third party payors were compelled  
26 to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted  
27  
28

1 third party payors, physicians, and consumers, and was designed to convince them of both the  
2 therapeutic and economic value of CELEBREX.

3 61. Defendants represented that CELEBREX was similar to ibuprofen and naproxen  
4 but was superior because it lacked any of the common gastrointestinal adverse side effects  
5 associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). For instance,  
6 NSAIDS can, in certain patients, cause gastrointestinal perforations, ulcers and bleeding with  
7 long-term use. Defendants promoted CELEBREX as a safe and effective alternative that would  
8 not have the same deleterious and painful impact on the gut, but that would be just as effective, if  
9 not more so, for pain relief.

10 62. CELEBREX possessed dangerous and concealed or undisclosed side effects,  
11 including the increased risk of serious cardiovascular events, such as heart attacks, unstable  
12 angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as  
13 strokes. In addition, CELEBREX was no more effective than traditional and less expensive  
14 NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and  
15 gastrointestinal bleeding. Defendants chose not to warn about these risks and dangers.

16 63. Defendants knew of these risks before the U.S. Food and Drug Administration (the  
17 "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed,  
18 omitted, and concealed these serious safety risks and denied inefficacy in its promotion,  
19 advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and  
20 concealment of this important information enabled CELEBREX to be sold to, and purchased, or  
21 paid for by, the Consumers at a grossly inflated price.

22 64. Consequently, CELEBREX captured a large market share of anti-inflammatory  
23 drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2  
24 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in  
25 the same family of drugs.

26 65. Because Defendants engaged in a promotional and marketing campaign that  
27 featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer  
28



1 drug than other drugs in its class, while uniformly failing to disclose the health risks of  
2 CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the  
3 cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed  
4 the truth about CELEBREX, Defendants would not and could not have reaped the billions of  
5 dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission,  
6 suppression, and obfuscation of the truth.

7 66. The Defendants intentionally, deliberately, knowingly, and actively concealed,  
8 omitted, suppressed, and obfuscated important and material information regarding the risks,  
9 dangers, defects, and disadvantages of CELEBREX from Plaintiff, the public, the medical  
10 community, and the regulators. This concealment and omission was deliberate, knowing, active,  
11 and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and  
12 prevented Plaintiff from obtaining all the material information that would be important to their  
13 decisions as reasonable persons to purchase, pay for, and/or use CELEBREX.

14 67. Defendants' systematic, active, knowing, deliberate, and uniform concealment,  
15 omissions, suppression, and conduct caused Plaintiff to purchase, pay for, and/or use  
16 CELEBREX; and caused Plaintiff's losses and damages as asserted herein.

17 68. Had Defendants done adequate testing prior to approval and "market launch," the  
18 defendants' scientific data would have revealed significant increases in stroke and myocardial  
19 infarction amongst the intended population of CELEBREX consumers. Adequate testing would  
20 have shown that CELEBREX possessed serious side effects. Defendants should have taken  
21 appropriate measures to ensure that their defectively designed product would not be placed in the  
22 stream of commerce and/or should have provided full and proper warnings accurately and fully  
23 reflecting the scope and severity of symptoms of those side effects should have been made.

24 69. In fact, post-market approval data did reveal increased risks of clotting, stroke and  
25 myocardial infarction, but Defendants intentionally suppressed this information in order for them  
26 to gain significant profits from continued CELEBREX sales.

1           70. Defendants' failure to conduct adequate testing and/or additional testing prior to  
2 "market launch" was based upon their desire to generate maximum financial gains for themselves  
3 and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

4           71. At the time Defendants manufactured, advertising, and distributed CELEBREX to  
5 consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding  
6 the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants  
7 knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but  
8 instead would purchase other cheaper and safer NSAID drugs.

9                           **CLAIMS FOR RELIEF**

10                           **FIRST CLAIM FOR RELIEF**

11                           **Negligence**

12           72. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
13 fully set forth herein and further allege as follows.

14           73. Defendants owed Plaintiffs a duty to exercise reasonable care when designing,  
15 manufacturing, marketing, advertising, distributing, and selling CELEBREX. This duty included  
16 the duty not to introduce a pharmaceutical drug, such as CELEBREX, into the stream of  
17 commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side  
18 effects.  
19

20           74. At all relevant times to this action, Defendants owed a duty to properly warn  
21 Plaintiffs and the Public of the risks, dangers and adverse side effects of their pharmaceutical  
22 drug CELEBREX.

23           75. Defendants breached their duties by failing to exercise ordinary care in the  
24 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
25 marketing, promotion, advertising and selling of CELEBREX, including: failing to use due care  
26 in the preparation and development of CELEBREX to prevent the aforementioned risk of injuries  
27 to individuals when the drugs were ingested;

28           76. failing to use due care in the design of CELEBREX to prevent the aforementioned

1 risk of injuries to individuals when the drugs were ingested;

2 77. failing to conduct adequate pre-clinical testing and research to determine the safety  
3 of CELEBREX;

4 78. failing to conduct adequate post-marketing surveillance and exposure studies to  
5 determine the safety of CELEBREX;

6 79. failing to completely, accurately and in a timely fashion, disclose the results of the  
7 pre-marketing testing and post-marketing surveillance and testing to Plaintiffs, consumers, the  
8 medical community, and the FDA;

9 80. failing to accompany CELEBREX with proper warnings regarding all possible  
10 adverse side effects associated with the use of CELEBREX;

11 81. failing to use due care in the manufacture, inspection, and labeling of CELEBREX  
12 to prevent the aforementioned risk of injuries to individuals who used CELEBREX;

13 82. failing to use due care in the promotion of CELEBREX to prevent the  
14 aforementioned risk of injuries to individuals when the drugs were ingested;

15 83. failing to use due care in the sale and marketing of CELEBREX to prevent the  
16 aforementioned risk of injuries to individuals when the drugs were ingested;

17 84. failing to use due care in the selling of CELEBREX to prevent the aforementioned  
18 risk of injuries to individuals when the drugs were ingested;

19 85. failing to provide adequate and accurate training and information to the sales  
20 representatives who sold CELEBREX;

21 86. failing to provide adequate and accurate training and information to healthcare  
22 providers for the appropriate use of CELEBREX: and

23 87. being otherwise reckless, careless and/or negligent.

24 88. Despite the fact that Defendants knew or should have known that CELEBREX  
25 caused unreasonable and dangerous side effects which many users would be unable to remedy by  
26 any means, Defendants continued to promote and market CELEBREX to consumers, including  
27 Plaintiffs, when safer and more effective methods of pain relief were available.

28 89. Defendants were, or should have been, had they exercised reasonable care, in  
possession of evidence demonstrating that CELEBREX caused serious side effects. Nevertheless,

1 they continued to market their products by providing false and misleading information with  
2 regard to the safety and efficacy of CELEBREX.

3 90. Defendants knew or should have known that consumers such as Plaintiffs would  
4 foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

5 91. As a direct and proximate consequence of Defendants' acts, omissions, and  
6 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
7 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
8 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
9 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
10 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
11 preexisting conditions and activation of latent conditions, and other losses and damages.  
12 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
13 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

14 92. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
15 and deliberate disregard for the value of human life and the rights and safety of consumers,  
16 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
17 punish Defendants and deter them from similar conduct in the future.

18 93. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
19 compensatory damages, and exemplary and punitive damages together with interest, the costs of  
20 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

## 21 **SECOND CLAIM FOR RELIEF**

### 22 **Strict Liability**

23 94. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
24 fully set forth herein and further allege as follows.

25 95. At all times relevant to this action, Defendants were suppliers of CELEBREX,  
26 placing the drug into the stream of commerce. CELEBREX was expected to and did reach  
27 Plaintiffs without substantial change in the condition in which it was manufactured and sold.

28 96. CELEBREX was unsafe for normal or reasonably anticipated use.

97. CELEBREX was defective in design or formulation because when it left the hands



1 of the manufacturer and/or supplier, it was unreasonably dangerous and more dangerous than an  
2 ordinary consumer would expect. CELEBREX was also defective and unreasonably dangerous in  
3 that the foreseeable risk of injuries from CELEBREX exceeded the benefits associated with the  
4 design and/or formulation of the product.

5 98. Celebrex is unreasonably dangerous: a) in construction or composition; b) in  
6 design; c) because an adequate warning about the product was not provided; d) because it does  
7 not conform to an express warranty of the manufacturer about the product.

8 99. The characteristics of Celebrex that render it unreasonably dangerous under  
9 existed at the time the product left the control of the manufacturer or resulted from a  
10 reasonably anticipated alteration or modification of the product.

11 100. The CELEBREX manufactured and supplied by Defendants was also defective  
12 due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate  
13 reporting regarding the results of the clinical trials, testing and study. Defendants failed to  
14 perform adequate testing before exposing Plaintiffs to the medication, testing which would have  
15 shown that CELEBREX had the potential to cause serious side effects including strokes like that  
16 which affected Plaintiffs.

17 101. The CELEBREX manufactured and supplied by Defendants was defective due to  
18 inadequate post-marketing warnings or instructions because, after Defendants knew or should  
19 have known of the risk of injuries from CELEBREX, they failed to provide adequate warnings to  
20 the medical community and the consumers, to whom they were directly marketing and  
21 advertising CELEBREX; and, further, it continued to affirmatively promote CELEBREX as safe  
22 and effective.

23 102. CELEBREX was manufactured, distributed, tested, sold, marketed, advertised and  
24 promoted defectively by Defendants, and as a direct and proximate cause of Defendants'  
25 defective design of CELEBREX, Plaintiffs used CELEBREX rather than other safer and cheaper  
26 NSAIDs. As a result, Plaintiffs suffered the personal injuries described above.

27 103. Information given by Defendants to the medical community and to the consumers  
28 concerning the safety and efficacy of CELEBREX, especially the information contained in the  
advertising and promotional materials, did not accurately reflect the potential side effects of

1 CELEBREX.

2 104. Had adequate warnings and instructions been provided, Plaintiffs would not have  
3 taken CELEBREX as they did, and would not have been at risk of the harmful side effects  
4 described herein.

5 105. Defendants acted with conscious and deliberate disregard of the foreseeable harm  
6 caused by CELEBREX.

7 106. Plaintiffs could not, through the exercise of reasonable care, have discovered  
8 CELEBREX's defects or perceived the dangers posed by the drug.

9 107. As a direct and proximate consequence of Defendants' acts, omissions, and  
10 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
11 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
12 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
13 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
14 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
15 preexisting conditions and activation of latent conditions, and other losses and damages.  
16 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
17 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

18 108. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
19 and deliberate disregard for the value of human life and the rights and safety of consumers,  
20 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
21 punish Defendants and deter them from similar conduct in the future.

22 109. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
23 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
24 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

25 **THIRD CLAIM FOR RELIEF**

26 **Breach of Express Warranty**

27 110. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
28 fully set forth herein and further allege as follows.

111. Defendants expressly represented to Plaintiffs and other consumers and the

1 medical community that CELEBREX was safe and fit for its intended purposes, that it was of  
2 merchantable quality, that it did not produce any dangerous side effects, particularly any  
3 unwarned-of side effects, and that it was adequately tested.

4 112. These warranties came in the form of:

5 a. Defendants' public written and verbal assurances of the safety and efficacy  
6 of CELEBREX;

7 b. Press releases, interviews and dissemination via the media of promotional  
8 information, the sole purpose of which was to create an increased demand for CELEBREX,  
9 which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to  
10 the long-term ingestion of CELEBREX;

11 c. Verbal and written assurances made by Defendants regarding CELEBREX  
12 and downplaying the risk of injuries associated with the drug;

13 d. False and misleading written information, supplied by Defendants, and  
14 published in the Physician's Desk Reference on an annual basis, upon which physicians relied in  
15 prescribing CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

16 e. advertisements.

17 113. The documents referred to above were created by and at the direction of  
18 Defendants.

19 114. Defendants knew or had reason to know that CELEBREX did not conform to these  
20 express representations in that CELEBREX is neither as safe nor as effective as represented, and  
21 that CELEBREX produces serious adverse side effects.

22 115. CELEBREX did not and does not conform to Defendants' express representations  
23 because it is not safe, has numerous and serious side effects, including unwarned-of side effects,  
24 and causes severe and permanent injuries.

25 116. Plaintiffs, other consumers, and the medical community relied upon Defendants'  
26 express warranties.

27 117. As a direct and proximate consequence of Defendants' acts, omissions, and  
28 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred

1 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
2 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
4 preexisting conditions and activation of latent conditions, and other losses and damages.  
5 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
6 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

7 118. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
8 and deliberate disregard for the value of human life and the rights and safety of consumers,  
9 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
10 punish Defendants and deter them from similar conduct in the future.

11 119. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
12 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
13 suit and attorneys' fees and such other and further relief as this Court deems just and proper.

#### 14 **FOURTH CLAIM FOR RELIEF**

##### 15 **Breach of Implied Warranty**

16 120. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
17 fully set forth herein and further allege as follows.

18 121. Defendants manufactured, distributed, advertised, promoted, and sold  
19 CELEBREX.

20 122. At all relevant times, Defendants knew of the use for which CELEBREX was  
21 intended and impliedly warranted the product to be of merchantable quality and safe and fit for  
22 such use.

23 123. Defendants were aware that consumers, including Plaintiffs, would use  
24 CELEBREX for treatment of pain and inflammation and for other purposes.

25 124. Plaintiffs and the medical community reasonably relied upon Defendants'  
26 judgment and expertise to only sell them or allow them to prescribe CELEBREX only if it was  
27 indeed of merchantable quality and safe and fit for its intended use. Consumers, including  
28 Plaintiffs, and the medical community, reasonably relied upon Defendants' implied warranty for  
CELEBREX.



125. CELEBREX reached consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

126. Defendants breached their implied warranty to consumers, including Plaintiffs; CELEBREX was not of merchantable quality or safe and fit for its intended use.

127. As a direct and proximate consequence of Defendants' acts, omissions, and misrepresentations described herein, Plaintiffs sustained serious injuries and related losses. Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

128. Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendants and deter them from similar conduct in the future.

129. WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages and punitive and exemplary damages together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

#### **FIFTH CLAIM FOR RELIEF**

##### **Fraudulent Misrepresentation & Concealment**

130. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows.

131. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of CELEBREX, and their intentional dissemination of promotional and marketing information about CELEBREX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about CELEBREX's risks and

1 harms to doctors and consumers.

2 132. Defendants made fraudulent affirmative misrepresentations with respect to  
3 CELEBREX in the following particulars:

4 a. Defendants represented through their labeling, advertising, marketing  
5 materials, detail persons, seminar presentations, publications, notice letters, and regulatory  
6 submissions that CELEBREX had been tested and found to be safe and effective for the treatment  
7 of pain and inflammation; and

8 b. Defendants represented that CELEBREX was safer than other alternative  
9 medications.

10 133. Defendants made affirmative misrepresentations; and fraudulently, intentionally  
11 and/or recklessly concealed material adverse information regarding the safety and effectiveness of  
12 CELEBREX.

13 134. Defendants made these misrepresentations and actively concealed adverse  
14 information at a time when Defendants knew or had reason to know that CELEBREX had defects  
15 and was unreasonably dangerous and was not what Defendants had represented to the medical  
16 community, the FDA and the consuming public, including Plaintiffs.

17 135. Defendants omitted, suppressed and/or concealed material facts concerning the  
18 dangers and risk of injuries associated with the use of CELEBREX including, but not limited to,  
19 the cardiovascular, cerebrovascular, and other serious health risks. Furthermore, Defendants'  
20 purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the  
21 serious nature of the risks associated with the use of CELEBREX in order to increase its sales.

22 136. The representations and concealment were undertaken by Defendants with an  
23 intent that doctors and patients, including Plaintiffs, rely upon them.

24 137. Defendants' representations and concealments were undertaken with the intent of  
25 defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and  
26 encourage the sale of CELEBREX.

27 138. Defendants' fraudulent representations evinced their callous, reckless, willful, and  
28 depraved indifference to the health, safety, and welfare of consumers, including Plaintiffs.

139. Plaintiffs' physician and Plaintiffs relied on and were induced by Defendants'

1 misrepresentations, omissions, and/or active concealment of the dangers of CELEBREX in  
2 selecting CELEBREX treatment.

3 140. Plaintiffs and the treating medical community did not know that the  
4 representations were false and were justified in relying upon Defendants' representations.

5 141. Had Plaintiffs been aware of the increased risk of side effects associated with  
6 CELEBREX and the relative efficacy of CELEBREX compared with other readily available  
7 medications, Plaintiffs would not have taken CELEBREX as he did.

8 142. As a direct and proximate consequence of Defendants' acts, omissions, and  
9 misrepresentations described herein, Plaintiffs sustained serious injuries and related losses.  
10 Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred  
11 and will continue to incur medical and related expenses. Plaintiffs also have suffered and will  
12 continue to suffer mental anguish, physical pain and suffering, diminished capacity for the  
13 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of  
14 preexisting conditions and activation of latent conditions, and other losses and damages.  
15 Plaintiffs also incurred direct medical losses and costs include care for hospitalization, physician  
16 care, monitoring, treatment, medications, and supplies. Plaintiffs have also suffered loss of wages.

17 143. Defendants' conduct was committed with knowing, conscious, wanton, willful,  
18 and deliberate disregard for the value of human life and the rights and safety of consumers,  
19 including Plaintiffs, thereby entitling Plaintiffs to punitive and exemplary damages so as to  
20 punish Defendants and deter them from similar conduct in the future.

21 144. WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
22 compensatory damages, and punitive and exemplary damages together with interest, the costs of  
23 suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

### 24 **SIXTH CLAIM FOR RELIEF**

#### 25 **Unjust Enrichment**

26 145. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if  
27 fully set forth herein and further allege as follows.

28 146. At all times relevant to this action, Defendants were the manufacturers, sellers,  
and/or suppliers of CELEBREX.

1 147. Plaintiffs paid for CELEBREX for the purpose of managing their pain safely and  
2 effectively.

3 148. Defendants have accepted payment from Plaintiffs for the purchase of  
4 CELEBREX.

5 149. Plaintiffs did not receive the safe and effective pharmaceutical product for which  
6 she paid.

7 150. It is inequitable and unjust for Defendants to retain this money because Plaintiffs  
8 did not in fact receive the product Defendant represented CELEBREX to be.

9 151. WHEREFORE, Plaintiffs demand judgment against Defendants and seeks  
10 equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court  
11 deems just and proper.

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Plaintiffs request the following relief:

- 14 1. General damages in excess of the jurisdictional amount of this Court;  
15 2. Consequential damages;  
16 3. Disgorgement of profits;  
17 4. Restitution;  
18 5. Damages for loss of consortium, care, comfort, society and companionship in an  
19 amount within the jurisdiction of this Court and according to proof;  
20 6. Punitive and exemplary damages;  
21 7. Pre-judgment and post-judgment interest as provided by law;  
22 8. Recovery of Plaintiffs' costs including, but not limited to, discretionary Court  
23 costs of these causes, and those costs available under the law, as well as expert fees and attorneys'  
24 fees and expenses, and costs of this action; and  
25 9. Such other and further relief as the Court deems just and proper.

26 Dated: July 13, 2007

27 Respectively submitted,

28 By: Nawar Ward



1  
2 Andy D. Birchfield, Jr. (AL State Bar No. BIR006)  
3 Email: andy.birchfield@beasleyallen.com  
4 Gerald B. Taylor, Jr. (AL State Bar No. TAY026)  
5 Email: jerry.taylor@beasleyallen.com  
6 Navan Ward, Jr. (AL State Bar No. WAR062)  
7 Email: navan.ward@beasleyallen.com  
8 BEASLEY, ALLEN, CROW, METHVIN,  
9 PORTIS & MILES, P.C.  
10 Post Office Box 4160  
11 Montgomery, Alabama 36103-4160  
12 (334) 269-2343 telephone  
13 (334) 954-7555 facsimile

14 Attorneys for Plaintiff

15 **DEMAND FOR JURY TRIAL**

16 Plaintiffs demand a trial by jury on all claims so triable in this action.

17 Dated: July 13, 2007

18 Respectfully submitted,

19 By: Navan Ward Jr.

20 Andy D. Birchfield, Jr. (BIR006)  
21 Gerald B. Taylor, Jr. (TAY026)  
22 Navan Ward, Jr. (WAR062)  
23 BEASLEY, ALLEN, CROW, METHVIN,  
24 PORTIS & MILES, P.C.  
25 P. O. Box 4160  
26 Montgomery, Alabama 36103-4160  
27 Telephone: (334) 269-2343  
28 Facsimile: (334) 954-7555

ATTORNEYS FOR PLAINTIFF